Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: PCI Synthesis

[Docket No. DEA-896]

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: PCI Synthesis has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 30, 2021, PCI Synthesis, 9 Opportunity Way, Newburyport, Massachusetts 01950-0195, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Amphetamine	1100	II
Methamphetamine	1105	II

The company plans to develop manufacturing processes, conduct analytical method validation and conduct bulk product stability studies.

Brian S. Besser,

Acting Assistant Administrator.

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